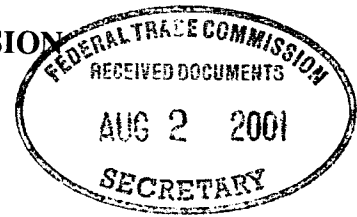


UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION



In the Matter of)
)
)

Schering-Plough Corporation,)
a corporation,)
)

Upsher-Smith Laboratories,)
a corporation,)
)

and)
)
)

American Home Products Corporation,)
a corporation.)
_____)

Docket No. 9297

**RESPONDENT SCHERING-PLOUGH CORPORATION'S JOINDER
IN AMERICAN HOME PRODUCTS CORPORATION'S MOTION
TO COMPEL COMPLAINT COUNSEL TO SEARCH
THE FEDERAL TRADE COMMISSION FOR RESPONSIVE DOCUMENTS**

Respondent Schering-Plough Corporation ("Schering") respectfully joins American Home Products Corporation's ("AHP") July 23, 2001 motion to compel complaint counsel to search the files of the Federal Trade Commission ("FTC") for documents responsive to its First Request for the Production of Documents. Schering's document requests to complaint counsel are substantially similar to those issued by AHP, and complaint counsel has taken the same positions with respect to both Schering's and AHP's requests. Accordingly, Schering hereby adopts the arguments made by, and joins in, AHP's motion.

I. RELEVANT DISCOVERY FACTS

On June 19, 2001, Schering issued its First Request for the Production of Documents ("the Request") on the Federal Trade Commission. The Request is attached as Exhibit A. All of

Schering's requests relate directly to the core allegations in the Complaint in this matter, to the Commission's theory of harm, and to Schering's potential defenses. Despite Schering's requests, complaint counsel have refused to search for responsive documents where they are reasonably likely to be found.¹ Instead, complaint counsel have taken the same position with Schering as they have with AHP. Complaint counsel have refused, on an across-the-board and non-negotiable basis, (1) to search any file owners outside of "those persons employed by the Commission in the Division of Health Care Products and Services of the Bureau of Competition, and in the Bureau of Economics that were assigned to or actually worked on" FTC File No. 991-0256 or this litigation,² or (2) to search the files of any other closed or pending investigation.³ See Complaint Counsel's Objections to Schering's Request at Exhibit C, General Objection Nos. 4 and 7; Declaration of Charles A. Loughlin, attached as Exhibit B.

Several of Schering's requests on their face seek documents from investigations other than File No. 991-0256. See Request Nos. 1-6, 9, 10, 28, 32-34, 42. Indeed, Request Nos. 32-34 request documents from two other investigations by name, the Hoechst/Andrx and Abbott/Geneva matters. Still other requests at least implicitly ask for a reasonable search beyond File No. 991-0256. See Request Nos. 11-15, 17-25, 27, 29-31, 35, 40-42, 44-48.

Moreover, complaint counsel's own statements suggest that they are relying on responsive documents from investigations other than File No. 991-0256. For example, during

¹ As noted in the Declaration of Charles A. Loughlin, counsel for Schering have attempted in good faith to resolve this dispute with complaint counsel, but have reached an impasse. See Exhibit B, ¶ 2.

² Complaint counsel have indicated that they have searched for documents in the files of the Bureau of Competition's Division of International Antitrust, Division of Policy and Evaluation, and the Commission's Office of Public Affairs in response to AHP's First Request, and the FTC has produced responsive documents from those files to Schering.

³ Complaint counsel have stated that they searched the FTC's Congressional Relations office, but that they have only searched files relating to File No. 991-0256, not files relating to other investigations.

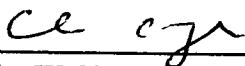
oral argument on Schering's Motion for Partial Dismissal on July 25, 2001, complaint counsel equated the Schering/AHP/Upsher settlements with the Hoechst/Andrx and Abbott/Geneva matters. See Transcript of Pretrial Hearing, July 25, 2001 at pp. 39-40, 42-43, 45, 50-51, 58-59, attached as Exhibit D. Although the FTC relies on the court decisions relating to the Hoechst/Andrx and Abbott/Geneva agreements to support its position in this matter, complaint counsel have refused to produce those agreements to Schering. This refusal is despite Schering's explicit requests for those agreements by name. See Requests Nos. 32-34.

II. ARGUMENT AND CONCLUSION

Schering joins AHP's Motion to Compel, filed July 23, 2001. Schering's document requests are substantially the same as AHP's, and complaint counsel have offered similar objections to the scope of the search. Indeed, Schering and complaint counsel have agreed that, with respect to Schering's document requests, both parties will abide the Court's ruling on AHP's Motion to Compel. Accordingly, Schering does not believe that additional briefing or argument on its joinder is necessary, or that its joinder should in any way delay briefing or decision on AHP's motion.

Respectfully submitted,

Dated: August 2, 2001



John W. Nields, Jr.
Marc G. Schildkraut
Laura S. Shores
Charles A. Loughlin
HOWREY SIMON ARNOLD & WHITE LLP
1299 Pennsylvania Ave., N.W.
Washington, D.C. 20004
(202) 783-0800

Attorneys for Respondent
Schering-Plough Corporation

CERTIFICATE OF SERVICE

I hereby certify that this 2nd day of August, 2001, I caused an original, one paper copy and an electronic copy of Schering-Plough Corporation's Joinder in American Home Products Corporation's Motion to Compel Complaint Counsel to Search the Federal Trade Commission for Responsive Documents to be filed with the Secretary of the Commission, and that two paper copies and an electronic copy were served by hand upon:

Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
Room 104
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

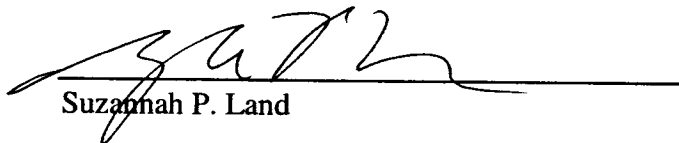
and one paper copy was hand delivered upon:

Richard A. Feinstein
Assistant Director
Bureau of Competition
Federal Trade Commission
Room 3114
601 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Karen Bokar
Bureau of Competition
Federal Trade Commission
Washington, D.C.
601 Pennsylvania Ave, N.W.
Washington, D.C. 20580

Christopher Curran
White & Case LLP
601 13th St., N.W.
Washington, D.C. 20005

Cathy Hoffman
Arnold & Porter
555 12th St., N.W.
Washington, D.C. 20004



Suzannah P. Land

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

In the Matter of)	
)	
Schering-Plough Corporation,)	
a corporation,)	
)	
Upsher-Smith Laboratories,)	Docket No. 9297
a corporation,)	
)	
and)	
)	
American Home Products Corporation,)	
a corporation.)	

**RESPONDENT SCHERING-PLOUGH CORPORATION'S FIRST REQUEST FOR THE
PRODUCTION OF DOCUMENTS**

Pursuant to Federal Trade Commission ("FTC") Rules of Practice for Adjudicative Proceedings ("Rule of Practice") 3.31 and 3.37, 16 C.F.R. §§ 3.31 and 3.37, and in accordance with the Court's Scheduling Order dated May 3, 2001, Respondent Schering-Plough Corporation, through the undersigned counsel, submits these requests for production of documents to the FTC. Respondent requests that the FTC begin producing documents or things responsive to these requests, within its possession, custody or control, within twenty (20) business days for inspection and copying by counsel for respondent at the offices of Howrey Simon Arnold & White, 1299 Pennsylvania Ave., NW, Washington, D.C. 20004-2402, in accordance with the Instructions set forth below.

INSTRUCTIONS AND DEFINITIONS

1. As used herein, "agreement" means any oral or written contract, arrangement or understanding, whether formal or informal, between two or more persons, together with modifications or amendments thereto.

2. As used herein, "ANDA" means an Abbreviated New Drug Application filed with the FDA pursuant to 21 U.S.C. § 355(j), including but not limited to the original application and any supplements thereto.
3. As used herein, "Schering" means Schering-Plough Corporation, and its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting on its behalf.
4. As used herein, "Upsher" means Upsher-Smith Laboratories and its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting on its behalf.
5. As used herein, "AHP" means American Home Products Corporation and its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting on its behalf.
6. As used herein, "ESI" shall refer to ESI Lederle, Incorporated, and its predecessors, successors, assigns and present and/or former affiliates and subsidiaries and any of its respective officers, directors, employees, agents, attorneys, representatives, economic consultants, lobbyists, public relations consultants or any person acting on its behalf.
7. As used herein, "Abbott/Geneva Matter" means the inquiry, investigation, adjudication, enforcement proceeding, or settlement by consent decree or other means by the FTC or any other governmental agency in connection with or relating in any manner to the agreements between Abbott Laboratories, Incorporated and Geneva Pharmaceuticals or of any other activities related to FTC Docket No. C-3945.
8. As used herein, "Hoechst/Andrx Matter" means the inquiry, investigation, adjudication, enforcement proceeding, or settlement by consent decree or other means by the FTC or any

11. As used herein, "FDA" means the United States Food and Drug Administration, including without limitation its employees, scientists, technicians, agents, examiners, laboratories, consultants and special governmental employees.
12. As used herein, "FTC" means the United States Federal Trade Commission, including without limitation its employees, investigators, agents, consultants and special governmental employees.
13. As used herein, "formulary" means a list of prescription medications covered under a pharmacy benefit plan maintained by a governmental entity or third-party payor.
14. As used herein, "Schering Investigation" means the investigation by the FTC of Schering, Upsher, AHP, and ESI, FTC File No. 9910256, and the pending litigation against those parties by the FTC, identified as FTC Docket No. 9297.
15. As used herein, "Schering/Upsher Settlement" means the Settlement Agreement between Schering and Upsher, dated June 17, 1997.
16. As used herein, "Schering/ESI Settlement" means the Settlement Agreement between Schering and ESI, dated June 19, 1998.
17. As used herein, "person" includes any natural person, corporate entity, sole proprietorship, partnership, association, governmental entity, or trust.
18. As used herein, "relates" means addresses, analyzes, concerns, contains, comments on, discusses, explains, identifies, refers to, pertains to, describes, forms the basis for, evidences or constitutes, deals with, and the term "relating" means addressing, analyzing, concerning, containing, commenting on, discussing, explaining, identifying, referring to, pertaining to, describing, evidencing or constituting, or dealing with.
19. As used herein, "180-Day Rule" refers to the provision(s) of the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), or FDA regulation, practice, understanding, or interpretation that allows, in some circumstances, for a 180-day period of marketing exclusivity for the generic drug of the first ANDA applicant.

20. The connectives “and” and “or” shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside of its scope.
21. The term “all” shall be construed as all and each, and the term “each” shall be construed as all and each.
22. The use of the singular form of any word includes the plural, and vice versa.
23. Except for privileged materials, produce each responsive document in its entirety by including all attachments and all pages, regardless of whether they relate to the specified subject matter. Submit any appendix, table, or other attachment by either physically attaching it to the responsive document or clearly marking it to indicate the responsive document to which it corresponds. Except for privileged material, do not mask, cut, expunge, edit, or delete any responsive document or portion thereof in any manner.
24. Unless otherwise stated, the scope of this request is from January 1, 1995, through the present and is continuing in nature. If, after producing documents, the FTC obtains or becomes aware of any further documents, or information responsive to this request for production of documents, the FTC is required to produce to Schering such additional documents and/or to provide to Schering such additional information.
25. Compliance with this document request requires a search of all documents in the possession, custody, or control of the FTC’s current or former officers, directors, employees, agents, or representatives, whether or not such documents are on the premises of the FTC. If any person is unwilling to have his or her files searched, or is unwilling to produce responsive documents, the FTC must provide counsel serving this request with the following information as to each such person: his or her name, address, telephone number, and relationship to the FTC.
26. If any requested documents cannot be produced in full, produce the remainder and state whatever information, knowledge, or belief the FTC has concerning the unproduced portion.

27. In addition to hard-copy documents, the search will include all the FTC's electronically stored data. Sources of such data include, but are not limited to, the following:
- (a) Desktop personal computers ("PCs") and workstations; PCs, workstations, minicomputers and mainframes used as file servers, application servers, or mail servers; laptops, notebooks, hand-held devices and other portable computers available for shared use; and home computers used for work related purposes;
 - (b) Backup disks and tapes, archive disks and tapes, and other forms of offline storage, whether stored onsite with the computer used to generate them, stored offsite in another facility or stored offsite by a third-party, such as in a disaster recovery center; and
 - (c) Computers and related offline storage used by agents, consultants, and other persons as defined herein, which may include persons who are not employees of the FTC or who do not work on FTC premises.
28. The FTC will submit all documents, including electronically-stored documents, in hard copy. In addition to the hard copies, the FTC will submit the electronically-stored documents in machine readable form.
29. The source and location of each responsive document shall be designated, including the person from who it was obtained. Responsive documents from each person's files shall be produced together, in file folders or with other enclosures that segregate the files by request number. If a document is responsive to more than one request, it shall be produced in response to the request to which it is primarily responsive. An index of responsive documents is requested in hard copy and machine-readable form identifying for each document produced: (1) the identification and consecutive control number; (2) the numbered request(s) to which it is responsive; (3) the person from whom the document was obtained; and (4) for documents generated by the recipient, the person and/or file name or number from which it was obtained.
30. In the event that the FTC withholds any document on the basis that it is privileged, subject to work-product immunity, or is otherwise excludable from discovery, the FTC is requested to list such documents by request number and to provide the following information:
- (a) the identity of the authors;

- (b) the identity of all recipients;
- (c) the date of the document;
- (d) the subject matter or purpose of the document or report;
- (e) the nature of the relationship between the authors and counsel with sufficient particularity to sustain the asserted privilege;
- (f) the basis for the privilege, including applicable statutory or regulatory citations; (g) whether the document was prepared in anticipation of litigation, and if the document was prepared in anticipation of litigation, in addition, provide the names of parties, case number, and the date of the complaint filing; and
- (g) any other information necessary to reveal the basis upon which the document is withheld to provide Schering with sufficient information to determine whether the stated basis for withholding the document is proper.

31. If any document responsive to these requests once existed but has been destroyed, lost, discarded or is otherwise not available for production, the recipient shall identify in writing each such document, including the date of the document's creation, a description of the document's subject matter, the name and address of each person who prepared, received, viewed, or had possession, custody or control of the document or otherwise had knowledge of its subject matter, and a statement of the circumstances under which the document was destroyed, lost, discarded or why such document is otherwise not available for production.

32. As used herein, the term "communication" means any exchange, transfer, or dissemination of information, regardless of the means by which it is accomplished and includes internal communications within one entity or between and among two or more entities.

33. If the FTC has produced documents responsive to this request in the course of the Schering Investigation, those documents need not be produced again. If there are no documents responsive to any particular request, the FTC shall state so in its answer to the document request.

34. Unless otherwise stated, each paragraph or subparagraph herein shall be construed independently and without reference to any other paragraph or subparagraph for purpose of limitation.

35. As used herein, the term "identify" means

- a. when used in reference to a document, to (1) set forth (i) the name and address of the author of the document; (ii) the name and address of all recipients of a copy of the document; and (iii) the date of the document; and (2) identify and describe the content of the document in detail.
- b. when used in reference to a natural person, to set forth that person's (i) name; (ii) present title or position and area of responsibility; (iii) present or last known business and home address; and (iv) present or last known employer. For any person identified, if any of the above information was different at the time with which a particular document request is concerned, supply both current information and such different information as applies to the time period in question.
- c. when used in reference to a corporation or any other entity, to set forth the address of its principal place of business.
- d. when used in reference to a "communication," state the (i) date of the communication; (ii) nature and substance of the communication; (iii) identity of each person who was present at or who participated in such communication; (iv) type of communication (*e.g.*, letter, memorandum, telegram, telephone conversation, etc.); and (v) identity of each document related in any way to such communication.

DOCUMENT REQUESTS

Request No. 1: All documents submitted to the FTC voluntarily or through compulsory process by Upsher, AHP, ESI or any third party in connection with or relating in any manner to the Schering Investigation, the Schering/Upsher Settlement, the Schering/ESI Settlement, patent settlements or partial patent settlements between an innovator or brand pharmaceutical company and a generic company, or potassium supplements, niacin supplements,

cholesterol-lowering products, generic enalapril and/or other cardiac pharmaceutical products, or generic buspirone and/or other anti-anxiety pharmaceutical products.

Request No. 2: All document indexes, lists, and/or logs, including privilege logs, submitted to the FTC voluntarily or through compulsory process by Upsher, AHP, ESI or any third party in connection with or relating in any manner to the Schering Investigation, the Schering/Upsher Settlement, the Schering/ESI Settlement, patent settlements or partial patent settlements between an innovator or brand pharmaceutical company and a generic company, or potassium supplements, niacin supplements, cholesterol-lowering products, generic enalapril and/or other cardiac pharmaceutical products, or generic buspirone and/or other anti-anxiety pharmaceutical products.

Request No. 3: All civil investigative demands, subpoenas or other formal or informal requests for materials and information issued by the FTC to Upsher, AHP, ESI or third parties in connection with or relating in any manner to the Schering Investigation, the Schering/Upsher Settlement, the Schering/ESI Settlement, patent settlements or partial patent settlements between an innovator or brand pharmaceutical company and a generic company, or potassium supplements, niacin supplements, cholesterol-lowering products, generic enalapril and/or other cardiac pharmaceutical products, or generic buspirone and/or other anti-anxiety pharmaceutical products.

Request No. 4: All transcripts, minutes, or recorded recollections of all interviews, depositions, investigational hearings, or formal informal or sworn statements, including all exhibits thereto, taken by the FTC of or from Upsher, AHP, ESI or third parties in connection with or relating in any manner to the Schering Investigation, the Schering/Upsher Settlement, the Schering/ESI Settlement, patent settlements or partial patent settlements between an innovator or brand pharmaceutical company and a generic company, or potassium supplements, niacin supplements, cholesterol-lowering products, generic enalapril and/or other cardiac pharmaceutical products, or generic buspirone and/or other anti-anxiety pharmaceutical products.

Request No. 5: All statements, including but not limited to responses to interrogatories, responses to civil investigative demands and subpoenas, statements, memoranda and white papers, and affidavits and declarations provided to the FTC by Upsher, AHP, ESI or third parties in connection with or relating in any manner to the Schering Investigation, the Schering/Upsher Settlement, the Schering/ESI Settlement, patent settlements or partial patent settlements between an innovator or brand pharmaceutical company and a generic company, or potassium supplements, niacin supplements, cholesterol-lowering products, generic enalapril and/or other cardiac pharmaceutical products, or generic buspirone and/or other anti-anxiety pharmaceutical products.

Request No. 6: All communications, including but not limited to letters, notes, documents relating to telephonic communications or meetings, electronic mail messages or voice mail messages, between and among the FTC and Upsher, AHP, ESI or any third party in connection with or relating in any manner to the Schering Investigation, the Schering/Upsher Settlement, the Schering/ESI Settlement, patent settlements or partial patent settlements between an innovator or brand pharmaceutical company and a generic company, or potassium supplements, niacin supplements, cholesterol-lowering products, generic enalapril and/or other cardiac pharmaceutical products, or generic buspirone and/or other anti-anxiety pharmaceutical products.

Request No. 7: All documents sufficient to identify each person with whom the FTC communicated in connection with or relating in any manner to the Schering Investigation.

Request No. 8: All documents related to any of the parties listed in the FTC's initial disclosures.

Request No. 9: All documents reflecting statements made by Upsher, AHP, ESI or any third parties in meetings, interviews, or other communications with the FTC in connection with or relating in any manner to the Schering Investigation, the Schering/Upsher Settlement, the Schering/ESI Settlement, patent settlements or partial patent settlements between an innovator or brand pharmaceutical company and a generic company, or potassium supplements, niacin

supplements, cholesterol-lowering products, generic enalapril and/or other cardiac pharmaceutical products, or generic buspirone and/or other anti-anxiety pharmaceutical products.

Request No. 10: All documents relating to the actual or potential sales, marketing or promotion of any potassium supplement, niacin supplement, cholesterol-lowering product, generic cardiac pharmaceutical product, or generic anti-anxiety pharmaceutical product, which may have been provided to, gathered, collected, or received by the FTC in connection with the Schering Investigation or any other Commission proceeding, investigation or enforcement action.

Request No. 11: All documents reflecting the actual or potential sale, price, revenues, and profits of any potassium supplement, niacin supplement, cholesterol-lowering product, generic enalapril and/or other cardiac pharmaceutical products, or generic buspirone and/or other anti-anxiety pharmaceutical products, including but not limited to:

- (a) gross and net sales to all customers in units and dollars;
- (b) gross number and dollar value of promotional sample units distributed;
- (c) sales returns in units and dollars;
- (d) cost of goods sold in dollars;
- (e) gross and net profit in dollars;
- (f) sales, promotion, or marketing expenses;
- (g) the list price and wholesale acquisition cost;
- (h) product returns in units and dollars; and
- (i) rebates, credits, allowances, chargebacks, and any other adjustment to price.

Request No. 12: All documents, including those provided by third parties, that reflect any analysis with respect to (1) the sales of any potassium supplement and the extent to which these products may compete against each other; (2) the sales of any cholesterol-reducing product and the extent to which these products may compete against each other; (3) the sales of any niacin supplement and the extent to which these products may compete against each other; (4)

the extent to which sales of the products in (1) (2) and/or (3) above may respond to and/or may be affected by variations in price or manufacturer discounts, rebates, credits or other price adjustments; and (5) the extent to which sales of the products in (1) (2) and/or (3) above may respond to and/or may be affected by regulations by third-party payors, insurers, and other health-care providers that encourage or require the use of generic drugs in lieu of their branded counterpart.

Request No. 13: All documents which reflect in any way standards of care for the treatment of insufficient levels of potassium.

Request No. 14: All documents which reflect in any way standards of care for the treatment of high cholesterol.

Request No. 15: All documents which reflect in any way the substitutability of any potassium supplement for any other potassium supplement.

Request No. 16: All documents sufficient to identify third party payors who maintain prescription pharmaceutical formularies or the government entities with whom the FTC communicated in connection with or relating in any manner to the Schering Investigation.

Request No. 17: All documents which relate in any manner to the categories into which prescription pharmaceutical products are grouped in formularies, including categories of drug types and categories used for determining co-payments or reimbursement amounts for individual participants and/or payments to pharmacies.

Request No. 18: All documents which describe any process or criteria used to determine the pharmaceutical products to be included in any formulary.

Request No. 19: All documents which reflect in any manner the policies or criteria for making any initial classification in formularies as well as any reclassification of any previously classified pharmaceutical product in subsequent formulary listings.

Request No. 20: All documents which describe the formularies in which K-Dur® has been listed.

Request No. 21: All documents which relate in any way to programs, campaigns or activities undertaken by governmental entities and/or third-party payors which are designed to encourage the use or substitution of any potassium, cholesterol-lowering, or other cardiac pharmaceutical product for any other potassium, cholesterol-lowering, or other cardiac pharmaceutical product.

Request No. 22: All documents which relate in any way to the reimbursements paid by any governmental entity or third-party payor for potassium supplements.

Request No. 23: All documents that relate in any way to the negotiation of contracts or other agreements regarding discounts, rebates, credits, allowances, chargebacks and other price adjustments between government entities or third party payors and any manufacturer or distributor of potassium supplements.

Request No. 24: All documents that relate in any way to the negotiations of contracts or other agreements between vendors and any manufacturer of potassium supplements regarding, but not limited to, supply, inventory, pricing, and/or sales.

Request No. 25: All prescription benefit policies or riders maintained by any government entities or third-party payors that apply to potassium supplements.

Request No. 26: All documents relating in any manner to the Schering Investigation given or transmitted to any FTC Commissioner by the Bureau of Competition or the Bureau of Economics.

Request No. 27: All documents that relate to the effect on a prescription drug's sales or number of prescriptions of the inclusion of that prescription drug, or a competing prescription drug, on formularies or other prescription pharmaceutical benefit plans.

Request No. 28: All documents, transcripts, statements, submissions or other communications between the FTC and any other agency or instrumentality of the federal government, including but not limited to the FDA and Congress, that relates in any manner to the 180-Day Rule; the Schering Investigation; the Schering/Upsher Settlement; the Schering/ESI

Settlement; or any other settlement or partial settlement of patent litigation involving an innovator or brand name pharmaceutical company and a generic company.

Request No. 29: All documents relating to the FTC's understanding of the 180-Day Rule and the FDA's application of the 180-Day Rule, including, but not limited to, the FTC's knowledge and opinions concerning the state of the law.

Request No. 30: All documents that relate to the 180-Day Rule.

Request No. 31: All documents that relate in any manner to any allegations in the complaint issued in the Schering Investigation, FTC Docket No. 9297.

Request No. 32: All documents, transcripts, statements, submissions or other communications that relate to the Hoechst/Andrx Matter or the Abbott/Geneva Matter, including but not limited to the agreements between the parties in those cases.

Request No. 33: All documents, transcripts, statements, submissions or other communications that relate to the FTC's decision not to bring an action against Zenith Goldline in connection with Zenith Goldline's agreement with Abbott Laboratories with respect to the product at issue in the Abbott/Geneva Matter.

Request No. 34: All communications and/or documents relating to the statement found in the Analysis to Aid Public Comment submitted with the proposed Andrx/Hoechst Consent Decree that “[b]ased on the FTC’s investigation, it does not appear that there was any delay in the entry into the market of a generic version of Cardizem CD by Andrx or any other potential manufacturer, or that the conduct or agreement at issue delayed consumer access to a generic version of Cardizem CD.”

Request No. 35: All documents and/or articles relating to descriptions, policy considerations, and discussions of legal and economic implications relating to the Drug Price Competition and Patent Term Restoration Act of 1984 (“Hatch-Waxman”).

Request No. 36: All communications and/or documents between and among the FTC and the FDA on the status of, and FDA approval for, the application for the bioequivalents or

generic versions of K-Dur® filed by Upsher, AHP, or ESI, Andrx Corporation, KV Pharmaceuticals, Elan Pharmaceutical Technologies, and/or any other entity.

Request No. 37: All communications and/or documents between and among the FTC and any third party on the status of and final FDA approval for the application for the bioequivalents or generic versions of K-Dur® filed by Upsher, AHP, or ESI, Andrx Corporation, KV Pharmaceuticals, Elan Pharmaceutical Technologies, or any other entity.

Request No. 38: All documents relating to the product encompassed by Upsher's ANDA for a generic version of K-Dur 20, including but not limited to documents obtained from the FDA, Upsher and/or any third party.

Request No. 39: All documents relating to the product encompassed by ESI's ANDA for a generic version of K-Dur 20, including but not limited to documents obtained from the FDA, ESI, AHP, and/or any third party.

Request No. 40: All documents relating to any of the products Schering licensed from Upsher-Smith, including but not limited to documents obtained from the FDA, Upsher, and/or any third party.

Request No. 41: All documents relating to any of the products Schering licensed from ESI, including but not limited to documents obtained from the FDA, ESI, and/or any third party.

Request No. 42: All speeches, comments, or statements made by the FTC relating to any issues implicated in or related to the Schering Investigation, including but not limited to the entry of generic drugs into pharmaceutical markets, the investigation of patent settlements, the settlement of patent disputes, and the 180-Day Rule.

Request No. 43: All communications or documents relating to the issue of patent infringement with respect to the patent for K-Dur®.

Request No. 44: All documents related to the effect on a brand name drug's sales, profits, prescriptions and/or market share of the entry of generic competitors.

Request No. 45: All documents related to the effect on a generic drug's sales, profits, prescriptions and/or market share of the entry of generic competitors.

Request No. 46: All documents that support, refute, or in any way relate to the allegations in paragraph 17 of the Complaint in this matter.

Request No. 47: All documents that support, refute, or in any way relate to the allegations in paragraphs 18 and 19 of the Complaint in this matter.

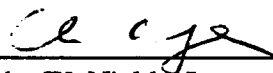
Request No. 48: All documents that support, refute, or in any way relate to the allegations in paragraphs 20-25 of the Complaint in this matter.

Request No. 49: All documents that support, refute, or in any way relate to the allegations in paragraphs 26-30 of the Complaint in this matter.

Request No. 50: All documents that relate to any request for advice received from 1990 to present by the FTC pursuant to 16 C.F.R. §§ 1.1-1.4 relating in any way to the settlement of patent infringement litigation, including all documents that reflect any oral or written advice or other response provided by the FTC.

Request No. 51: All documents identified in, or otherwise used by you to draft, your responses to Schering's First Set or Interrogatories.

Of Counsel:



John W. Nields, Jr.
Marc G. Schildkraut
Laura S. Shores
Charles A. Loughlin
HOWREY SIMON ARNOLD & WHITE LLP
1299 Pennsylvania Ave., N.W.
Washington, D.C. 20004
(202) 783-0800

Attorneys for Respondent
Schering-Plough Corporation

Dated: June 19, 2001

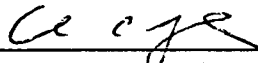
CERTIFICATE OF SERVICE

I hereby certify that this 19th day of June 2001, a copy of the foregoing Respondent Schering-Plough Corporation's First Request For The Production Of Documents was served by electronic mail and overnight delivery upon:

Christopher Curran
White & Case LLP
601 13th St., N.W.
Washington, D.C. 20005

Cathy Hoffman
Arnold & Porter
555 12th Street, N.W.
Washington, D.C. 20004

Yaa Apori
Bureau of Competition
Federal Trade Commission
601 Pennsylvania Avenue, N.W.
Washington, D.C. 20580



Charles A. Loughlin

**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION**

In the Matter of)	
)	
)	
Schering-Plough Corporation,)	
a corporation,)	
)	Docket No. 9297
Upsher-Smith Laboratories,)	
a corporation,)	
)	
and)	
)	
American Home Products Corporation,)	
a corporation.)	
)	

**DECLARATION OF CHARLES A. LOUGHLIN IN SUPPORT OF
RESPONDENT SCHERING-PLOUGH CORPORATION'S JOINDER
IN AMERICAN HOME PRODUCTS CORPORATION'S MOTION TO COMPEL**

I, Charles A. Loughlin, declare as follows:

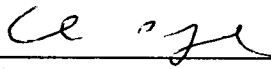
1. I am a partner at the law firm of Howrey Simon Arnold & White, counsel to Respondent Schering-Plough Corporation ("Schering"). My business address is 1299 Pennsylvania Avenue, N.W., Washington, D.C. 20004.
2. Counsel for Schering have negotiated in good faith with complaint counsel to resolve the dispute over the scope of complaint counsel's search for documents responsive to Schering's First Request for the Production of Documents. The parties are still working to resolve certain issues related to document production obligations. However, an impasse was reached on complaint counsel's scope of search when complaint counsel stated that they did not intend to search beyond a certain limited set of files and fileowners. The parties have not been able to resolve the dispute.

3. The FTC first raised objections to the scope of Schering's requests in its July 9, 2001 Objections and Responses to Schering's First Request for the Production of Documents. Complaint counsel stated that complaint counsel would only search the files of employees of the Division of Health Care Products and Services of the Bureau of Competition, and the Bureau of Economics who have worked on or were assigned to the Schering/AHP/Upsher matter, File No. 991-0256. Complaint counsel further refused to search any files other than those from File No. 991-0256.
4. On July 26, 2001, I, along with Suzannah P. Land, participated in a conference call with complaint counsel Yaa Apori and Steve Vieux. During this call, complaint counsel again indicated that they do not intend to search for responsive documents in any investigations other than the pre-complaint investigation and litigation in this matter. Complaint counsel repeated that they only intend to search for responsive documents in the files of those individuals within the Bureaus of Competition and Economics that worked on this pre-complaint investigation and litigation.
5. On July 30, 2001, I wrote to Mr. Vieux, confirming the positions taken by complaint in our July 26, 2001 discussion.
6. On July 31, Mr. Vieux called in response to my July 30th letter. Mr. Vieux reiterated that complaint counsel do not intend to search for responsive documents in any files other than those from the Schering/AHP/Upsher matter, File No. 991-0256. Mr. Vieux also reiterated that complaint counsel would only search the files of employees of the Division of Health Care Products and Services of the Bureau of Competition and the Bureau of Economics who have worked on or were assigned to File No. 991-0256. Mr. Vieux stated, however, that complaint counsel had searched the files of the Bureau of

Competition's Division of International Antitrust, Division of Policy and Evaluation, and the Commission's Office of Public Affairs in response to AHP's and Schering's document requests, and have produced responsive documents . Mr. Vieux also stated that complaint counsel had searched the Commission's Congressional Relations office, but had limited its search to files related to the Schering/AHP/Upsher matter, File No. 991-0256.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on August 2, 2001



Charles A. Loughlin

**UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION**

In the Matter of

SCHERING-PLOUGH CORPORATION,
a corporation,

UPSHER-SMITH LABORATORIES,
a corporation,

and

**AMERICAN HOME PRODUCTS
CORPORATION,**
a corporation.

Docket No. 9297

**COMPLAINT COUNSEL'S OBJECTIONS AND RESPONSES TO RESPONDENT
SCHERING-PLOUGH CORPORATION'S FIRST REQUEST FOR THE PRODUCTION
OF DOCUMENTS**

Pursuant to Federal Trade Commission ("FTC") Rules of Practice Section 3.37(b), 16 C.F.R. § 3.37(b), complaint counsel submits these Objections and Responses to Respondent Schering-Plough Corporation's First Set of Document Requests. The full text of each document request is set out below followed by our respective objections and responses. Our provision of a response and production of any document shall not constitute a waiver of any applicable objection, privilege or other right.

GENERAL OBJECTIONS

The following general objections apply to each of Schering-Plough Corporation's ("Schering") fifty-one (51) separately numbered document requests:

1. Complaint counsel objects to each request to the extent it seeks information

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

protected from disclosure by privilege, including, where applicable: (a) attorney-client privilege; (b) work-product privilege; (c) government deliberative-process privilege; (d) government informant privilege; (e) law enforcement investigatory-files privilege; and (f) any other applicable privilege. These objections include, but are not limited to the following:

- a. On the basis of both the work-product and attorney-client privileges, complaint counsel objects to each request which requires the production of: (a) notes, data compilations or summaries, internal communications, internal forms, or memoranda of FTC attorneys and staff; or (b) correspondence and documents exchanged between the FTC and its agents or non-testifying experts.
- b. On the basis of the work-product, attorney-client, and government deliberative-process privileges, complaint counsel objects to each request which requires the production of any communications, memoranda, or other internal documents exchanged (a) between FTC attorneys or staff; or (b) between FTC attorneys or staff and FTC Commissioners or their staff.
- c. On the basis of work-product privilege, complaint counsel objects to each request which requires the production of notes or reports of interviews with third parties.
- d. On the basis of the government informant privilege, complaint counsel objects to each request which requires the production of (a) complaints or documents received from confidential government informants without first redacting information that would identify these informants; (b) documents received from confidential government informants which by their nature would identify these informants; or (c) documents identifying confidential

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

government informants.

e. On the basis of the law enforcement investigatory-file privilege, complaint counsel objects to each request which requires the production of (a) correspondence or documents exchanged between the FTC and other law enforcement agencies; or (b) confidential documents received from other government agencies.

2. Complaint counsel objects to each request, instruction, or definition to the extent it seeks to impose obligations broader than those required or authorized by the Federal Trade Commission Rules of Practice for Adjudicatory Proceedings or any applicable order or rule of this Court.

3. Complaint counsel objects to each request to the extent that it seeks information not reasonably expected to yield information relevant to the allegations of the complaint, to the proposed relief, or to the defenses of any respondent.

4. Complaint counsel objects to each request as unduly burdensome to the extent that it purports to have complaint counsel conduct a search for responsive documents beyond those persons employed by the Commission in the Division of Health Care Products and Services of the Bureau of Competition, and in the Bureau of Economics that were assigned to or actually worked on the Schering-Plough, Corp., Upsher-Smith Laboratories and ESI Lederle, Inc. matter, FTC File No. 991-0256.

5. Complaint counsel objects to each request as premature to the extent it purports to require complaint counsel to provide, prior to the completion of discovery, "all" documents that support our position.

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

6. Complaint counsel objects to each request to the extent that it requires the inspection of documents produced by Schering as unduly burdensome, and on the ground that inspection of complaint counsel's files for documents produced by Schering would reveal work-product. Such material is known by complaint counsel already to be in the possession, custody, or control of Schering, or available to Schering from another source that is more convenient and less burdensome.

7. Complaint counsel objects to each request to the extent that it seeks production of confidential information acquired through compulsory process, or produced voluntarily in lieu of compulsory process, in other closed or open investigations other than Schering-Plough, Corp., Upsher-Smith Laboratories and ESI Lederle, Inc., FTC File No. 991-0256. Complaint counsel has no intention of relying on any documents produced in any investigation other than FTC File No. 991-0256. All documents produced in any investigation other than FTC File No. 991-0256 are privileged or confidential under 15 U.S.C. §§ 46(f), 57b-2(b), and 18a(h), as well as 16 C.F.R. § 4.10(d). Therefore, documents from other investigations may not be produced to respondents in this action. Complaint counsel further objects to these requests because information obtained in other matters, not relied on by Complaint counsel, is not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel further objects to these requests because searching other open or closed files would interfere with ongoing investigations, and the burden and expense of responding would outweigh its likely benefit.

8. Complaint counsel objects to each request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

Initial Disclosures.

9. Complaint counsel's decision to produce documents in response to Schering-Plough Corporation's First Set of Document Requests, notwithstanding any objections to any of the definitions, requests, or instructions, should not be construed as: (a) an admission that the produced documents are relevant; (b) a waiver of the general or specific objections asserted herein; or (c) an agreement that requests for similar information will be treated in a similar manner. Complaint counsel specifically reserves all objections as to the competency, relevancy, and admissibility of the information provided; all objections as to burden, vagueness, unintelligibility, over-breadth and ambiguity; and all rights to object to the use of any documents or information in any other proceeding.

10. The failure of complaint counsel to object to any specific request on a particular ground shall not be construed as a waiver of its rights to object on any additional ground(s). Complaint counsel reserves its rights to amend or supplement its objections and responses to these requests consistent with further investigation and discovery.

OBJECTIONS TO INSTRUCTIONS AND DEFINITIONS

11. Complaint counsel objects to Instruction 25 to the extent that it purports to require Complaint counsel to search for documents in the possession, custody, or control of the FTC's current or former employees, agents or representatives outside the premises of the FTC. To the extent that they require a search for responsive documents beyond those persons employed by the FTC in the Division of Health Care Products and Services of the Bureau of Competition, and in the Bureau of Economics that were assigned to, or actually worked on, the Schering-Plough

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

Corp., Upsher-Smith Laboratories and ESI Lederle, Inc. matter, FTC File No. 991-0256, complaint counsel further objects to this instruction as not reasonably expected to yield relevant or admissible evidence and unreasonably cumulative and duplicative. To the extent that Instruction 25 calls for a search for responsive documents in the possession, custody or control of current or former officers or directors, the FTC has no such positions.

12. Complaint counsel objects to Instruction 27 to the extent that it requires complaint counsel to search for electronically stored documents outside of the premises of the FTC. This is unduly burdensome, unreasonably cumulative and duplicative, and not reasonably calculated to lead to the discovery of admissible evidence.

13. Complaint counsel objects to Instruction 28 to the extent that it requires the production of electronically-stored documents in machine readable form. This instruction is unduly burdensome and duplicative of documents already submitted in hard copy.

14. Complaint counsel objects to Instruction 29 to the extent it requires complaint counsel to sort or otherwise segregate documents by request number. Complaint counsel will produce documents as they are kept in the usual course of business. Complaint counsel further objects to this Instruction's requirement for an index of non-privileged responsive documents. That calls for more than is required by the FTC Rules of Practice.

15. Complaint counsel objects to Instruction 30 as unduly burdensome to the extent that it purports to require Complaint counsel to identify, as to each document withheld based upon a claim of privilege, all of the information called for in subpart (e) and subpart (f), besides the basis of the privilege. That calls for more than is required by the FTC Rules of Practice.

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

16. Complaint counsel objects to the definition given to "identify" in Instruction 35 as overly broad and unduly burdensome.

RESPONSES AND OBJECTIONS TO DOCUMENT REQUESTS

Document Request No. 1: All documents submitted to the FTC voluntarily or through compulsory process by Upsher, AHP, ESI or any third party in connection with or relating in any manner to the Schering investigation, the Schering/Upsher Settlement, the Schering/ESI Settlement, patent settlements or partial patent settlements between an innovator or brand pharmaceutical company and a generic company, or potassium supplements, niacin supplements, cholesterol-lowering products, generic enalapril and/or other cardiac pharmaceutical products, or generic buspirone and/or other anti-anxiety pharmaceutical products.

Response: Complaint counsel objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures. Complaint counsel further objects to this request to the extent that it is overly broad, unduly burdensome, beyond the scope of this proceeding, and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 2: All document indexes, lists, and/or logs, including privilege logs, submitted to the FTC voluntarily or through compulsory process by Upsher, AHP, ESI or any third party in connection with or relating in any manner to the Schering Investigation, the Schering/Upsher Settlement, the Schering/ESI Settlement, patent settlements or partial patent settlements between an innovator or brand pharmaceutical company and a generic company, or potassium supplements, niacin supplements, cholesterol-lowering products, generic enalapril and/or other cardiac pharmaceutical products, or generic buspirone and/or other anti-anxiety pharmaceutical products.

Response: Complaint counsel objects to this request to the extent that it is

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures. Complaint counsel further objects to this request to the extent that it is overly broad, unduly burdensome, beyond the scope of this proceeding, and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 3: *All civil investigative demands, subpoenas or other formal or informal requests for materials and information issued by the FTC to Upsher, AHP, ESI or third parties in connection with or relating in any manner to the Schering Investigation, the Schering/Upsher Settlement, the Schering/ESI Settlement, patent settlements or partial patent settlements between an innovator or brand pharmaceutical company and a generic company, or potassium supplements, niacin supplements, cholesterol-lowering products, generic enalapril and/or other cardiac pharmaceutical products, or generic buspirone and/or other anti-anxiety pharmaceutical products.*

Response: Complaint counsel objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures. Complaint counsel further objects to this request to the extent that it is overly broad, unduly burdensome, beyond the scope of this proceeding, and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 4: *All transcripts, minutes, or recorded recollections of all interviews, depositions, investigational hearings, or formal informal or sworn statements, including all*

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

exhibits thereto, taken by the FTC of or from Upsher, AHP, ESI or third parties in connection with or relating in any manner to the Schering Investigation, the Schering/Upsher Settlement, the Schering/ESI Settlement, patent settlements or partial patent settlements between an innovator or brand pharmaceutical company and a generic company, or potassium supplements, niacin supplements, cholesterol-lowering products, generic enalapril and/or other cardiac pharmaceutical products, or generic buspirone and/or other anti-anxiety pharmaceutical products.

Response: Complaint counsel objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures. Complaint counsel further objects to this request to the extent that it is overly broad, unduly burdensome, beyond the scope of this proceeding, and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 5: *All statements, including but not limited to responses to interrogatories, responses to civil investigative demands and subpoenas, statements, memoranda and white papers, and affidavits and declarations provided to the FTC by Upsher, AHP, ESI or third parties in connection with or relating in any manner to the Schering Investigation, the Schering/Upsher Settlement, the Schering/ESI Settlement, patent settlements or partial patent settlements between an innovator or brand pharmaceutical company and a generic company, or potassium supplements, niacin supplements, cholesterol-lowering products, generic enalapril and/or other cardiac pharmaceutical products, or generic buspirone and/or other anti-anxiety pharmaceutical products.*

Response: Complaint counsel objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures. Complaint counsel further objects to this request to the extent that it is overly broad, unduly burdensome, beyond the scope of this proceeding, seeks information not

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

reasonably calculated to lead to the discovery of admissible evidence, and seeks material protected from disclosure under the attorney-client and work-product privileges. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 6: *All communications, including but not limited to letters, notes, documents relating to telephonic communications or meetings, electronic mail messages or voice mail messages, between and among the FTC and Upsher, AHP, ESI or any third party in connection with or relating in any manner to the Schering Investigation, the Schering/Upsher Settlement, the Schering/ESI Settlement, patent settlements or partial patent settlements between an innovator or brand pharmaceutical company and a generic company, or potassium supplements, niacin supplements, cholesterol-lowering products, generic enalapril and/or other cardiac pharmaceutical products, or generic buspirone and/or other anti-anxiety pharmaceutical products.*

Response: Complaint counsel objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures. Complaint counsel further objects to this request to the extent that it is overly broad, unduly burdensome, beyond the scope of this proceeding, seeks information not reasonably calculated to lead to the discovery of admissible evidence, and seeks material protected from disclosure under the attorney-client, work-product, and government informant privileges. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 7: *All documents sufficient to identify each person with whom the FTC communicated in connection with or relating in any manner to the Schering Investigation.*

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

Response: Complaint counsel objects to this request to the extent that it seeks the production of information that would identify confidential government informants on the ground that such information is protected from disclosure under the government-informant, work-product, and law enforcement investigatory-file privileges. Complaint counsel further objects to this request as overly broad to the extent it requests information identifying each and every individual "with whom the FTC communicated in connection with or relating in any manner to the Schering Investigation." Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 8: *All documents related to any of the parties listed in the FTC's initial disclosures.*

Response: Complaint counsel objects to this request to the extent that it is overly broad, beyond the scope of this proceeding, unduly burdensome and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel further objects to this request to the extent that it seeks information protected from disclosure by the work-product and government informant privileges. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 9: *All documents reflecting statements made by Upsher, AHP, ESI or any third parties in meetings, interviews, or other communications with the FTC in connection with or relating in any manner to the Schering Investigation, the Schering/Upsher Settlement, the Schering/ESI Settlement, patent settlements or partial patent settlements between an innovator or*

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

brand pharmaceutical company and a generic company, or potassium supplements, niacin supplements, cholesterol-lowering products, generic enalapril and/or other cardiac pharmaceutical products, or generic buspirone and/or other anti-anxiety pharmaceutical products.

Response: Complaint counsel objects to this request to the extent that it seeks information protected from disclosure by attorney-client, work-product, government informant, and government deliberative-process privileges. Complaint counsel further objects to this request to the extent that it is overly broad, beyond the scope of this proceeding, unduly burdensome and seeks information not reasonably calculated to lead to the discovery of admissible evidence. In addition, complaint counsel objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 10: *All documents relating to the actual or potential sales, marketing or promotion of any potassium supplement, niacin supplement, cholesterol-lowering product, generic cardiac pharmaceutical product, or generic anti-anxiety pharmaceutical product, which may have been provided to, gathered, collected, or received by the FTC in connection with the Schering Investigation or any other Commission proceeding, investigation or enforcement action.*

Response: Complaint counsel objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures. Complaint counsel further objects to this request to the extent that it is overly broad, beyond the scope of this proceeding, unduly burdensome, and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 11: *All documents reflecting the actual or potential sale, price, revenues, and profits of any potassium supplement, niacin supplement, cholesterol-lowering product, generic enalapril and/or other cardiac pharmaceutical products, or generic buspirone and/or other anti-anxiety pharmaceutical products, including but not limited to:*

- (a) *gross and net sales to all customers in units and dollars;*
- (b) *gross number and dollar value of promotional sample units distributed;*
- (c) *sales returns in units and dollars;*
- (d) *cost of goods sold in dollars;*
- (e) *gross and net profit in dollars;*
- (f) *sales, promotion, or marketing expenses;*
- (g) *the list price and wholesale acquisition cost;*
- (h) *product returns in units and dollars; and*
- (i) *rebates, credits, allowances, chargebacks, and any other adjustment to price.*

Response: Complaint counsel objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures. Complaint counsel further objects to this request to the extent that it is overly broad, beyond the scope of this proceeding, unduly burdensome and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel responds that it will produce responsive documents not produced previously and not covered by our objections.

Document Request No. 12: *All documents, including those provided by third parties, that reflect any analysis with respect to (1) the sales of any potassium supplement and the extent to which these products may compete against each other; (2) the sales of any cholesterol-reducing product and the extent to which these products may compete against each other; (3) the sales of any niacin supplement and the extent to which these products may compete against each other;*

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

(4) the extent to which sales of the products in (1) (2) and/or (3) above may respond to and/or may be affected by variations in price or manufacturer discounts, rebates, credits or other price adjustments; and (5) the extent to which sales of the products in (1) (2) and/or (3) above may respond to and/or may be affected by regulations by third-party payors, insurers, and other health-care providers that encourage or require the use of generic drugs in lieu of their branded counterpart.

Response: Complaint counsel objects to this request to the extent that it seeks information protected from disclosure by attorney-client, work-product, government informant, and government deliberative-process privileges. Complaint counsel further objects to this request to the extent that it is overly broad, beyond the scope of this proceeding, unduly burdensome and seeks information not reasonably calculated to lead to the discovery of admissible evidence. In addition, complaint counsel objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 13: *All documents which reflect in any way standards of care for the treatment of insufficient levels of potassium.*

Response: Complaint counsel objects to this request to the extent that it is overly broad, beyond the scope of this proceeding, unduly burdensome, and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel further objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures. Complaint counsel responds that it

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 14: All documents which reflect in any way standards of care for the treatment of high cholesterol.

Response: Complaint counsel objects to this request to the extent that it is overly broad, beyond the scope of this proceeding, unduly burdensome, and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel further objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 15: All documents which reflect in any way the substitutability of any potassium supplement for any other potassium supplement.

Response: Complaint counsel objects to this request to the extent that it is overly broad and unduly burdensome and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel further objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

Document Request No. 16: All documents sufficient to identify third party payors who maintain prescription pharmaceutical formularies or the government entities with whom the FTC communicated in connection with or relating in any manner to the Schering Investigation.

Response: Complaint counsel objects to this request to the extent it seeks information protected from disclosure under the government informant privilege. Complaint counsel further objects to this request to the extent it seeks the production of communications between the FTC and any other agency or instrumentality of the federal government on the ground that such communications are protected from disclosure under the law enforcement investigatory-file and work product privileges. Complaint counsel will produce any reasonably available responsive documents not covered by our objections.

Document Request No. 17: All documents which relate in any manner to the categories into which prescription pharmaceutical products are grouped in formularies, including categories of drug types and categories used for determining co-payments or reimbursement amounts for individual participants and/or payments to pharmacies.

Response: Complaint counsel objects to this request to the extent that it is overly broad and unduly burdensome and seeks information not reasonably calculated to lead to discovery of admissible evidence. Complaint counsel further objects to this request to the extent that it seeks information protected from disclosure by the work-product and government informant privileges. Complaint counsel will produce any reasonably available responsive documents not covered by our objections.

Document Request No. 18: All documents which describe any process or criteria used to determine the pharmaceutical products to be included in any formulary.

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

Response: Complaint counsel objects to this request to the extent that it is overly broad, beyond the scope of this proceeding, unduly burdensome, and seeks information not reasonably calculated to lead to discovery of admissible evidence. Complaint counsel further objects to this request to the extent that it seeks information protected from disclosure by the work-product and government informant privileges. Complaint counsel will produce any reasonably available responsive documents not covered by our objections.

Document Request No. 19: *All documents which reflect in any manner the policies or criteria for making any initial classification in formularies as well as any reclassification of any previously classified pharmaceutical product in subsequent formulary listings.*

Response: Complaint counsel objects to this request to the extent that it is overly broad, beyond the scope of this proceeding, unduly burdensome, and seeks information not reasonably calculated to lead to discovery of admissible evidence. Complaint counsel further objects to this request to the extent that it seeks information protected from disclosure by the work-product and government informant privileges. Complaint counsel will produce any reasonably available responsive documents not covered by our objections.

Document Request No. 20: *All documents which describe the formularies in which K-Dur® has been listed.*

Response: Complaint counsel objects to this request to the extent that it seeks information protected from disclosure by the work-product and government informant privileges.

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

Complaint counsel objects to this request as unduly burdensome to the extent that it seeks material that obviously should be in the possession, custody, or control of Schering, or available to Schering from another source that is more convenient and less burdensome. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 21: All documents which relate in any way to programs, campaigns or activities undertaken by governmental entities and/or third-party payors which are designed to encourage the use or substitution of any potassium, cholesterol-lowering, or other cardiac pharmaceutical product for any other potassium, cholesterol-lowering, or other cardiac pharmaceutical product.

Response: Complaint counsel objects to this request to the extent that it is overly broad, beyond the scope of this proceeding, unduly burdensome, and seeks information not reasonably calculated to lead to discovery of admissible evidence. Complaint counsel further objects to this request to the extent that it seeks information protected from disclosure by the work-product and government informant privileges. Complaint counsel will produce any reasonably available responsive documents not covered by our objections.

Document Request No. 22: All documents which relate in any way to the reimbursements paid by any governmental entity or third-party payor for potassium supplements.

Response: Complaint counsel objects to this request to the extent that it is overly broad and unduly burdensome and seeks information not reasonably calculated to lead to discovery of admissible evidence. Complaint counsel further objects to this request to the extent

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

that it seeks information protected from disclosure by the work-product and government informant privileges. Complaint counsel will produce any reasonably available responsive documents not covered by our objections.

Document Request No. 23: All documents that relate in any way to the negotiation of contracts or other agreements regarding discounts, rebates, credits, allowances, chargebacks and other price adjustments between government entities or third party payors and any manufacturer or distributor of potassium supplements.

Response: Complaint counsel objects to this request to the extent that it is overly broad and unduly burdensome and seeks information not reasonably calculated to lead to discovery of admissible evidence. Complaint counsel further objects to this request to the extent that it seeks information protected from disclosure by the work-product and government informant privileges. Complaint counsel will produce any reasonably available responsive documents not covered by our objections.

Document Request No. 24: All documents that relate in any way to the negotiations of contracts or other agreements between vendors and any manufacturer of potassium supplements regarding, but not limited to, supply, inventory, pricing, and/or sales.

Response: Complaint counsel objects to this request to the extent that it is overly broad and unduly burdensome and seeks information not reasonably calculated to lead to discovery of admissible evidence. Complaint counsel will produce any reasonably available responsive documents not covered by our objections.

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

Document Request No. 25: All prescription benefit policies or riders maintained by any government entities or third-party payors that apply to potassium supplements.

Response: Complaint counsel objects to this request to the extent that it is overly broad and unduly burdensome, and seeks information not reasonably calculated to lead to discovery of admissible evidence. Complaint counsel will produce any reasonably available responsive documents not covered by our objections.

Document Request No. 26: All documents relating in any manner to the Schering Investigation given or transmitted to any FTC Commissioner by the Bureau of Competition or the Bureau of Economics.

Response: Complaint counsel objects to this request as unduly burdensome since it requires complaint counsel to conduct a search for responsive documents beyond those persons employed by the Commission in the Bureaus of Competition and Economics that were assigned, or actually worked on, the Schering Investigation. Complaint counsel further objects to this request to the extent it seeks information protected from disclosure under the attorney-client, work-product, and government deliberative-process privileges.

Document Request No. 27: All documents that relate to the effect on a prescription drug's sales or number of prescriptions of the inclusion of that prescription drug, or a competing prescription drug, on formularies or other prescription pharmaceutical benefit plans.

Response: Complaint counsel objects to this request to the extent that it is overly broad and unduly burdensome and seeks information not reasonably calculated to the lead to the discovery of admissible evidence. Complaint counsel further objects to this request to the extent

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

that it seeks information protected from disclosure by the work-product and government informant privileges. Complaint counsel will produce any reasonably available responsive documents not covered by our objections.

Document Request No. 28: All documents, transcripts, statements, submissions or other communications between the FTC and any other agency or instrumentality of the federal government, including but not limited to the FDA and Congress, that relates in any manner to the 180-Day Rule; the Schering Investigation; the Schering/Upsher Settlement; the Schering/ESI Settlement; or any other settlement or partial settlement of patent litigation involving an innovator or brand name pharmaceutical company and a generic company.

Response: Complaint counsel objects to this request to the extent it seeks the production of communications between the FTC and any other agency or instrumentality of the federal government, on the grounds that such communications are protected from disclosure under the law enforcement investigatory-file, government deliberative-process, and work-product privileges. Complaint counsel further objects to this request on the ground that it is beyond the scope of this proceeding and seeks information not reasonably calculated to lead to the discovery of admissible information to the extent it refers to any other matter besides this one. Complaint counsel will produce any reasonably available responsive documents not covered by our objections.

Document Request No. 29: All documents relating to the FTC's understanding of the 180-Day Rule and the FDA's application of the 180-Day Rule, including, but not limited to, the FTC's knowledge and opinions concerning the state of the law.

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

Response: Complaint counsel objects to this request to the extent that it is overly broad and unduly burdensome and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel further objects to this request to the extent it seeks information protected from disclosure under the work-product and government deliberative-process privileges. Complaint counsel will produce any reasonably available responsive documents not covered by our objections.

Document Request No. 30: All documents that relate to the 180-Day Rule.

Response: Complaint counsel objects to this request to the extent that it is overly broad and unduly burdensome and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel further objects to this request to the extent it seeks information protected from disclosure under the work-product and government deliberative-process privileges. Complaint counsel will produce any reasonably available responsive documents not covered by our objections.

Document Request No. 31: All documents that relate in any manner to any allegations in the complaint issued in the Schering Investigation, FTC Docket No. 9297.

Response: Complaint counsel objects to this request to the extent it seeks information protected from disclosure by the attorney-client, work-product, and government deliberative-process privileges. Complaint counsel further objects to this request as premature to the extent it seeks information prepared by any expert in this matter. Such information shall be disclosed in

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

accordance with this Court's Scheduling Order. Complaint counsel also objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 32: All documents, transcripts, statements, submissions or other communications that relate to the Hoechst/Andrx Matter or the Abbott/Geneva Matter, including but not limited to the agreements between the parties in those cases.

Response: Complaint counsel objects to this request to the extent that it goes beyond the scope of this proceeding and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel further objects to this request to the extent it seeks information protected from disclosure under the attorney-client, work-product, and government deliberative-process privileges.

Document Request No. 33: All documents, transcripts, statements, submissions or other communications that relate to the FTC's decision not to bring an action against Zenith Goldline in connection with Zenith Goldline's agreement with Abbott Laboratories with respect to the product at issue in the Abbott/Geneva Matter.

Response: Complaint counsel objects to this request to the extent that it goes beyond the scope of this proceeding and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel further objects to this request to the extent it seeks information protected from disclosure under the attorney-client, work-product, and government deliberative-process privileges.

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

Document Request No. 34: All communications and/or documents relating to the statement found in the Analysis to Aid Public Comment submitted with the proposed Andrx/Hoechst Consent Decree that "[b]ased on the FTC's investigation, it does not appear that there was any delay in the entry into the market of a generic version of Cardizem CD by Andrx or any other potential manufacturer, or that the conduct or agreement at issue delayed consumer access to a generic version of Cardizem CD."

Response: Complaint counsel objects to this request to the extent that it goes beyond the scope of this proceeding and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel further objects to this request to the extent it seeks information protected from disclosure under the attorney-client, work-product, and government deliberative-process privileges.

Document Request No. 35: All documents and/or articles relating to descriptions, policy considerations, and discussions of legal and economic implications relating to the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman").

Response: Complaint counsel objects to this request to the extent that it is overly broad and unduly burdensome and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel further objects to this request to the extent it seeks information protected from disclosure under the attorney-client, work-product, and government deliberative-process privileges. Complaint counsel will produce any reasonably available responsive documents not covered by our objections.

Document Request No. 36: All communications and/or documents between and among the FTC and the FDA on the status of, and FDA approval for, the application for the bioequivalents or generic versions of K-Dur® filed by Upsher, AHP, or ESI, Andrx Corporation, KV Pharmaceuticals, Elan Pharmaceutical Technologies, and/or any other entity.

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

Response: Complaint counsel objects to this request to the extent it seeks the production of communications between the FTC and the U.S. Food and Drug Administration or any other federal law enforcement agency on the ground that such communications are protected from disclosure under the law enforcement investigatory-file and work-product privileges.

Complaint counsel will produce any reasonably available responsive documents not covered by our objections.

Document Request No. 37: All communications and/or documents between and among the FTC and any third party on the status of and final FDA approval for the application for the bioequivalents or generic versions of K-Dur® filed by Upsher, AHP, or ESI, Andrx Corporation, KV Pharmaceuticals, Elan Pharmaceutical Technologies, or any other entity.

Response: Complaint counsel objects to this request to the extent it seeks information protected from disclosure under the government informant and work-product privileges.

Complaint counsel further objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections. Complaint counsel will produce any reasonably available responsive documents not covered by our objections that were not previously produced.

Document Request No. 38: All documents relating to the product encompassed by Upsher's ANDA for a generic version of K-Dur 20, including but not limited to documents obtained from the FDA, Upsher and/or any third party.

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

Response: Complaint counsel objects to this request to the extent it seeks information protected from disclosure under the law enforcement investigatory-files, government informant, and work-product privileges. Complaint counsel further objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 39: *All documents relating to the product encompassed by ESI's ANDA for a generic version of K-Dur 20, including but not limited to documents obtained from the FDA, ESI, AHP, and/or any third party.*

Response: Complaint counsel objects to this request to the extent it seeks information protected from disclosure under the law enforcement investigatory-files, government informant, and work-product privileges. Complaint counsel further objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 40: *All documents relating to any of the products Schering licensed from Upsher-Smith, including but not limited to documents obtained from the FDA, Upsher, and/or any third party.*

Response: Complaint counsel objects to this request to the extent it seeks information protected from disclosure under the law enforcement investigatory-files, government informant, and work-product privileges. Complaint counsel further objects to this request to the extent that

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures, and to the extent that it is beyond the scope of this proceeding and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 41: All documents relating to any of the products Schering licensed from ESI, including but not limited to documents obtained from the FDA, ESI, and/or any third party.

Response: Complaint counsel objects to this request to the extent it seeks information protected from disclosure under the law enforcement investigatory-files, government informant, and work-product privileges. Complaint counsel further objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures, and to the extent that it is beyond the scope of this proceeding and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 42: All speeches, comments, or statements made by the FTC relating to any issues implicated in or related to the Schering Investigation, including but not limited to the entry of generic drugs into pharmaceutical markets, the investigation of patent settlements, the settlement of patent disputes, and the 180-Day Rule.

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

Response: Complaint counsel objects to this request to the extent that it is overly broad, unduly burdensome, beyond the scope of this proceeding and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel further objects to this request to the extent it seeks information protected from disclosure under the attorney-client, work-product, and government deliberative-process privileges. Complaint counsel will produce any responsive documents not covered by our objections.

Document Request No. 43: *All communications or documents relating to the issue of patent infringement with respect to the patent for K-Dur®.*

Response: Complaint counsel objects to this request to the extent that it seeks information protected from disclosure under the attorney-client, work-product, and government deliberative-process privileges. Complaint counsel further objects to this request as unduly burdensome to the extent that it seeks material known by complaint counsel already to be in the possession, custody, or control of Schering, or available to Schering from another source that is more convenient and less burdensome. Furthermore, complaint counsel already has provided to Schering a copy of all documents produced by Respondents Upsher and AHP during the FTC's pre-complaint investigation of File No. 991-0256. Schering's inspection of those documents would be more convenient and less burdensome.

Document Request No. 44: *All documents related to the effect on a brand name drug's sales, profits, prescriptions and/or market share of the entry of generic competitors.*

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

Response: Complaint counsel objects to this request to the extent that it is overly broad, unduly burdensome, beyond the scope of this proceeding, and seeks information not reasonably calculated to lead to the discovery of admissible information. Complaint counsel further objects to this request to the extent it seeks information protected from disclosure under the attorney-client, work-product, and government deliberative-process privileges. In addition, complaint counsel objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Document Request No. 45: All documents related to the effect on a generic drug's sales, profits, prescriptions and/or market share of the entry of generic competitors.

Response: Complaint counsel objects to this request to the extent that it is overly broad, unduly burdensome, beyond the scope of this proceeding, and seeks information not reasonably calculated to lead to the discovery of admissible information. Complaint counsel further objects to this request to the extent it seeks information protected from disclosure under the attorney-client, work-product, and government deliberative-process privileges. In addition, complaint counsel objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosure. Complaint counsel responds that it will produce reasonably available responsive documents not produced previously and not covered by our objections.

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

Document Request No. 46: All documents that support, refute, or in any way relate to the allegations in paragraph 17 of the Complaint in this matter.

Response: Complaint counsel objects to this request to the extent it seeks information protected from disclosure by the attorney-client, work-product, and government deliberative-process privileges. Complaint counsel further objects to this request as premature to the extent it seeks information prepared by any expert in this matter. Such information shall be disclosed in accordance with this Court's Scheduling Order. Complaint counsel also objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures.

Document Request No. 47: All documents that support, refute, or in any way relate to the allegations in paragraphs 18 and 19 of the Complaint in this matter.

Response: Complaint counsel objects to this request to the extent it seeks information protected from disclosure by the attorney-client, work-product, and government deliberative-process privileges. Complaint counsel further objects to this request as premature to the extent it seeks information prepared by any expert in this matter. Such information shall be disclosed in accordance with this Court's Scheduling Order. Complaint counsel also objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures.

Document Request No. 48: All documents that support, refute, or in any way relate to the allegations in paragraphs 20-25 of the Complaint in this matter.

Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

Response: Complaint counsel objects to this request to the extent it seeks information protected from disclosure by the attorney-client, work-product, and government deliberative-process privileges. Complaint counsel further objects to this request as premature to the extent it seeks information prepared by any expert in this matter. Such information shall be disclosed in accordance with this Court's Scheduling Order. Complaint counsel also objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures.

Document Request No. 49: *All documents that support, refute, or in any way relate to the allegations in paragraphs 26-30 of the Complaint in this matter.*

Response: Complaint counsel objects to this request to the extent it seeks information protected from disclosure by the attorney-client, work-product, and government deliberative-process privileges. Complaint counsel further objects to this request as premature to the extent it seeks information prepared by any expert in this matter. Such information shall be disclosed in accordance with this Court's Scheduling Order. Complaint counsel also objects to this request to the extent that it is unreasonably cumulative and duplicative in that it seeks documents already disclosed in the Initial Disclosures.

Document Request No. 50: *All documents that relate to any request for advice received from 1990 to present by the FTC pursuant to 16 C.F.R. §§ 1.1-1.4 relating in any way to the settlement of patent infringement litigation, including all documents that reflect any oral or written advice or other response provided by the FTC.*

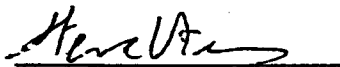
Complaint Counsel's Responses And Objections To Respondent Schering-Plough Corporation's First Request for the Production of Documents

Response: Complaint counsel objects to this request to the extent it is beyond the scope of this proceeding and seeks information not reasonably calculated to lead to the discovery of admissible evidence. Complaint counsel further objects to this request to the extent it seeks information protected from the government informant, work-product, and government deliberative-process privileges. Complaint counsel will produce any reasonably available responsive documents not covered by our objections.

Document Request No. 51: *All documents identified in, or otherwise used by you to draft, your responses to Schering's First Set of Interrogatories.*

Response: Subject to the foregoing general objections, and without waiving any of them, complaint counsel responds that it has already produced documents responsive to this request.

Respectfully Submitted,



Steve Vieux
Karen Bokar

Counsel Supporting the Complaint
Bureau of Competition
Federal Trade Commission
Washington, DC 20580

Dated: July 9, 2001


CERTIFICATE OF SERVICE

I, Steve Vieux, hereby certify that on July 9, 2001, I caused a copy of Complaint Counsel's Responses and Objections to Schering-Plough Corporation's First Request for the Production of Documents to be served upon the following persons by Federal Express and facsimile:

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Steve Vieux

In The Matter Of:

*SCHERING-PLOUGH CORP., UPSHER-SMITH
LABORATORIES AND AMERICAN HOME PRODUCTS CORP.*

PRETRIAL HEARING

July 25, 2001

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[1] got a generic equivalent, how much will you pay me not to
[2] market it, not to file it?

[3] MR. KADES: Not only is that agreement per se, it
[4] conceivably would be criminal.

[5] JUDGE: You're saying that an agreement that's
[6] effectively the same thing wrapped around this patent
[7] litigation settlement is still unlawful.

[8] MR. KADES: Yes. Your Honor, the complaint alleges
[9] first that Schering has monopoly power. It alleges that the
[10] entry of generic competition will significantly erode
[11] Schering's market share and profits.

[12] It further alleges that to protect those products —
[13] profits rather, Schering conspired with its two potential
[14] competitors, Upsher-Smith and AHP, paying them each millions
[15] of dollars to delay their entry.

[16] JUDGE: In the complaint, you've got a specific
[17] amount for one agreement and a not so specific amount on the
[18] other agreement. Is there a reason for that?

[19] MR. KADES: Yes, Your Honor.

[20] JUDGE: Again I haven't seen any of the agreements
[21] because we haven't started a trial, but...

[22] MR. KADES: Yes, Your Honor. At the time that the
[23] complaint was voted on by the Commission, we had more
[24] evidence through our investigation about the value of the
[25] licenses and the other products in the Upsher agreement, and

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[1] we felt confident in alleging that it was worth — the entire
[2] part — let me try that again, that the entire payment was
[3] for delayed.

[4] As to ESI, we've had significantly less discovery on
[5] the products that were licensed from ESI back to Schering, so
[6] therefore, we felt confident in alleging that the \$15 million
[7] that was paid unconditionally for settling the case was for
[8] delay.

[9] As to the remaining \$15 million, we had some evidence
[10] that even that may or may not be related to delay, and so we
[11] drafted that complaint's allegation differently.

[12] I think that Schering would agree with us, outside of
[13] the patent laws, that this sort of agreement would be illegal
[14] under the antitrust laws. Specifically in Palmer versus BRG,
[15] the Supreme Court found an antitrust violation when one
[16] company sold the product in Georgia. Its competitor agreed
[17] to stay out of that market, and they split royalties from the
[18] sales in Georgia. That's a simple market allocation.

[19] What's interesting in that case, Your Honor, is that
[20] that agreement was accomplished through a copyright license.
[21] They used an intellectual property license to set up that
[22] arrangement. The Supreme Court didn't even talk about
[23] whether the intellectual property had any defense to their
[24] activities.

[25] But there are actually much closer examples of

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[1] findings of illegality of this type of conduct, and here I
[2] specifically talk about the Cardizem and the Terazeson
[3] (phonetic) case.

[4] On the Cardizem case, a case which Your Honor
[5] probably knows better than I do, involved almost the exact
[6] same facts as you have alleged in this complaint. Hoechst,
[7] the branded manufacturer, paid Andrx, the first filer, an
[8] agreement for Andrx to stay off the market during the
[9] pendency of their patent case.

[10] The Court found that to be — the District Court in
[11] Michigan found that to be an antitrust violation, exact same
[12] structure as the agreement here, payment from brand to
[13] potential entrant. Potential entrant agrees not to enter the
[14] market. District Court ruled it's not only an antitrust
[15] violation but, in fact, a per violation.

[16] In the Terazeson case, once again, exact same facts
[17] basically. Abbott was the brand manufacturer. It made an
[18] agreement with Geneva. Under that agreement Abbott paid
[19] Geneva, and Geneva agreed to stay off the market during the
[20] pendency of the patent appeal.

[21] That case also had a second filer Zenith. Abbott
[22] paid Zenith. Zenith in return agreed to stay off the market
[23] until there was at least one other generic on the market.
[24] Once again those are exactly what like what we've alleged
[25] here.

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[1] JUDGE: Are you saying the agreements are similar,
[2] the terms of the agreement?

[3] MR. KADES: The terms of the agreement, yes.

[4] JUDGE: The material terms of the agreement.

[5] MR. KADES: Right, in this sense, that there's a
[6] payment from the brand to the generic, and the generic agrees
[7] to stay off the market for some period of time, which is
[8] exactly what we've alleged here.

[9] There was a payment from Schering to Upsher, and
[10] Upsher agreed to stay off the market until September 2001.
[11] There was a payment from Schering to ESI, and ESI agreed to
[12] stay off the market until January of 2004.

[13] Your Honor you'll notice both in the Cardizem and
[14] Terazeson cases, those involve patent disputes. The Courts
[15] specifically rejected the notion that they had to determine
[16] invalidity or non infringement. They found those agreements
[17] illegal without looking at invalidity or non infringement.

[18] Now, this raises a second point, that a patent does
[19] not give Schering the right to pay its competitors or its
[20] potential competitors not to compete, and Schering has
[21] provided no case law at all for that proposition. They
[22] cannot find a case where to settle a patent dispute, someone
[23] has just gone out and paid someone, a potential entrant, to
[24] delay their entry, not one.

[25] We've just cited you two, and we have the other

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[1] Supreme Court cases that we'll talk about in a minute.

[2] JUDGE: So you can refuse to allow anyone to use your
[3] patent. You can refuse to license. You can even refuse to
[4] use it yourself, but what you're saying, your position is you
[5] can't pay someone not to compete.

[6] MR. KADES: Exactly. I think to understand why
[7] Schering's argument is wrong as a matter of law, we have to
[8] look very close at the justification, which is that if
[9] Schering were to win its patent suit, then it can keep its
[10] product off the market until the end of the patent.

[11] Therefore, unless the patent is invalid or none
[12] infringed, in sort of a formalistic deduction, there can be
[13] no antitrust violation as long as the product comes to market
[14] before the end of the patent.

[15] But the problem is their justification, rationale is
[16] contradicted by the Supreme Court case law and the two drug
[17] settlement cases.

[18] Let's go back to Masonite. Now, in Masonite the
[19] patent holder licensed potential competitors to sell the
[20] patent holder products. The Supreme Court assumed the patent
[21] was valid, and nobody had a non infringed product.

[22] JUDGE: That also included price fixing.

[23] MR. KADES: That's right, Your Honor, but we'll get
[24] to why that doesn't make any difference, which is —

[25] JUDGE: Let's get to that now.

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[1] MR. KADES: Yes. It took me just a moment to shift
[2] gears.

[3] JUDGE: All right.

[4] MR. KADES: Your Honor, price fixing is a term. From
[5] an economic and legal sense, the Courts don't treat price
[6] fixing any different than market allocation, which is they
[7] do, and interesting enough, if you would look at the Cardizem
[8] decision, which once again to remind you involved these same
[9] sort of market allocations, that Court explicitly said that
[10] their agreement was a price fixing agreement.

[11] And I'm quoting, this is on page 709 of In Re:
[12] Cardizem litigation, 105 F SUP 2nd 682: "It," referring to
[13] the Andrx Hoechst agreement, "restricted competition from
[14] HMRI, the brand name drug manufacturer and Andrx —" I'm
[15] sorry. I misread it. Let me try that one more time.
[16] "It," meaning the Andrx Hoechst agreement,
[17] "restricted competition between HMRI, the brand name
[18] manufacturer and Andrx, the generic drug manufacturer,
[19] allocated the entire market for Cardizem CD and its
[20] bioequivalence to HMRI and allowed HMRI to maintain or fix
[21] the price of Cardizem CD at a noncompetitive level during the
[22] life of the agreement."

[23] So in trying to —

[24] JUDGE: If I've heard you right, isn't the Court
[25] implying terms of the agreement? Aren't they saying, Well,

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[1] the effect of this is that you've agreed to a market
[2] allocation. You've agreed to enter suit, Hoechst or HMRI,
[3] they've changed names three times, the pioneer drug company,
[4] by entering into agreement with the generic company, then
[5] they have among themselves effectively agreed to a market
[6] allocation 100 percent for the patent holder?

[7] MR. KADES: Yes, and then went on to say that that is
[8] the same as price fixing. If you look at the history of
[9] price fixing law, certainly price fixing doesn't require an
[10] agreement as to price levels. Courts have regularly found
[11] price fixing where you make an agreement that effects the
[12] price that could be charged in a marketplace.

[13] And from an economic sense it makes no — the
[14] distinction is totally irrelevant for the reasons that the
[15] Court in the Cardizem case said. There's no difference if
[16] you and I fix prices at the monopoly level and sell in the
[17] marketplace. Then if you — you pay me to stay out, you set
[18] the monopoly price. The effect is the same.

[19] So the attempt to distinguish Masonite is semantic
[20] and meaningless.

[21] (Discussion off the record.)

[22] MR. KADES: Your Honor, there's a second reason why
[23] this attempt to distinguish based on price fixing does
[24] Schering no good, because it still doesn't provide any
[25] support for their position because, even if it's price

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[1] fixing, it still contradicts their rule of law.

[2] Remember the rule of law is if someone is on the
[3] market selling prior to the patent expiration, that's more
[4] competition than if they've out of the market entirely.
[5] That's true in Masonite, whether it was price fixing, market
[6] allocation, whatever you want to call it. The result of that
[7] agreement was that these competitors who argued — who were
[8] infringing, were infringing the patent and therefore could
[9] have been kept off the market until the end of the agreement
[10] were allowed on the market by the licensing agreement, albeit
[11] with a requirement as to price fixing.

[12] JUDGE: So if I understand your interpretation of
[13] Masonite, you're saying that take out the price fixing, plug
[14] in another element like delay of entering the market, then
[15] you have an illegal agreement.

[16] MR. KADES: Say that one more time.

[17] JUDGE: If you agree to settle your patent
[18] litigation, and you add any element that's considered illegal
[19] under the law, then your agreement is invalid and unlawful?
[20] Doesn't have to be price fixing. It doesn't have to be price
[21] fixing. It can be market allocation.

[22] MR. KADES: I don't think if — that may be a little
[23] broader than what I'm saying, but I think if you look at
[24] Masonite, what the Court was concerned about is that you have
[25] these potential competitors who conceivably — who were a

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[1] threat to the monopolist power, that the monopolist said, Why
[2] don't you stop trying to compete with us and join our team,
[3] and I'll tell you what we'll do, we'll all share these
[4] monopoly profits that won't exist if you guys enter anyway,
[5] so we'll all be better off than if you enter so let's join
[6] this deal.
[7] In effect what the monopolist was doing was taking a
[8] share of the monopoly rent and buying off its competitors.
[9] The mechanism was a price fixing agreement. They could have
[10] done it as Schering did it here, by just paying someone to
[11] stay out for a period of time.
[12] And this is why Masonite, the theory of the case is
[13] four-square within Masonite. It's consistent with Cardizem.
[14] It's consistent with Terazeson. It's consistent with the
[15] other cases we cite in our brief.
[16] Your Honor, the only case law Schering cites goes to
[17] the proposition that a patent holder has the right not to
[18] license. That's true. That also doesn't reach the conduct
[19] alleged here. The conduct alleged here was a payment for
[20] delayed entry.
[21] As such, the fact that Schering could have chosen not
[22] to license Upsher doesn't mean that they can license Upsher
[23] on any terms.
[24] In fact, as we quoted in the Masonite case, it
[25] explicitly said the right to license or not license doesn't

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[1] give you the right to license on lesser terms, which is
[2] precisely the argument they're making.
[3] They're saying because we don't have to license them
[4] at all, it must be legal for them to license them to come in
[5] halfway through. Maybe true, maybe not, but the issue is can
[6] they also pay their potential competitor to take that deal,
[7] to give — to share the monopoly profits with the potential
[8] competitor.
[9] JUDGE: Doesn't every license agreement have some
[10] delay built in? We agree you're going to license my patent,
[11] my product, whatever, and you're going to start next year or
[12] two years from now, so there is some delay built into any
[13] license agreement.
[14] MR. KADES: That's true.
[15] JUDGE: What you're saying is you can't pay for that
[16] delay.
[17] MR. KADES: Exactly. Your Honor, the third issue
[18] that we would like to address here is that the merits of the
[19] underlying patent dispute are not a necessary precondition to
[20] showing liability, and I have to say at least we remain
[21] slightly baffled as to the relation between that argument,
[22] Schering's argument that we need to show invalidity and non
[23] infringement, because if we had to show the patent was
[24] invalid and not infringed, I'm not sure what more we could do
[25] to show the outcome of the settlement was worse than the

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[1] litigation, having already proved that the patent was invalid
[2] or non infringed. I'm not sure if there's a relationship or
[3] there is an alternative.
[4] What we have to prove, however, is the agreement was
[5] anti-competitive, and what that rests on is what that payment
[6] was for in each of those agreements. If the payment was for
[7] delay, then as the complaint alleges, neither Schering,
[8] neither Upsher nor ESI would have agreed to their respective
[9] entry dates if they didn't get the money. So in the
[10] alternative world of an alternative settlement, you would
[11] have an earlier entry date.
[12] It also is the case that the entry date under the
[13] settlement must be better than what Schering expected to get
[14] by litigating because Schering was willing to pay \$60 million
[15] to Upsher to get that delay and was willing to pay up to \$30
[16] million to get delay from ESI.
[17] As Your Honor asked, and quite correct, Yes, this
[18] case comes down to whether we can prove that the agreement
[19] — that the payment was for delay, and we will prove that,
[20] but at this point we assume it because it's a motion to
[21] dismiss, and yes, that is the central focus of this case.
[22] We would also point out, Your Honor, that they can
[23] actually cite no primary case law, any case law that says an
[24] antitrust plaintiff has ever had to prove what the underlying
[25] merits of the litigation were.

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[1] To do so is really in some sense argumentative as a
[2] straw person because we could never do that. We can never go
[3] back in time and figure out what the probabilities are
[4] because at the time before the settlement, Your Honor,
[5] Schering and Upsher had conflicting interests. Schering
[6] wanted to show that the patent infringed or the product
[7] infringed, and Upsher wanted to show that it didn't
[8] infringe.
[9] Today both of them want to show that, Well, it
[10] probably did infringe or it was likely to infringe because
[11] that's critical to their argument on why they're legal, so we
[12] can never go back in time.
[13] Your Honor, as to the citation to Hovencamp, if I
[14] could point out, first of all, that obviously Hovencamp is
[15] secondary for it, and I think their use of Hovencamp reveals
[16] the danger of applying secondary authority broadly, because
[17] if you look closely at the Hovencamp section, he's dealing
[18] with almost entirely with a very specific type of patent
[19] disputes where they have blocking patents or patent
[20] inferences.
[21] And in that situation, you have two patents, one of
[22] which is going to trump, and someone is going to have the
[23] monopoly. There will be a monopoly. In these cases that's
[24] not the issue. The issue is whether there is an economic
[25] monopoly to begin with.

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[1] And so the danger of anti-competitive results here in
[2] this case is that the monopolist can buy off his competitor.
[3] JUDGE: So you're saying Hovencamp's analysis doesn't
[4] apply because we don't have the battle of patents in this
[5] situation.

[6] MR. KADES: We don't have a patent blocking patent.
[7] We don't have two people saying, My patent trumps, the other
[8] person saying, My patent trumps. If they go to trial one
[9] patent is going to trump, and they're going to have a
[10] monopoly.

[11] It's clearly different in a case where one person has
[12] a monopoly, and you go to trial, maybe the patent will win,
[13] but if you lose there's competition.

[14] The second thing is the standard under Hovencamp
[15] really has three elements. First, there's a bona fide
[16] dispute; second, that it must be a reasonable accommodation;
[17] and third, not worse than a reasonable outcome of the
[18] litigation.

[19] In that entire section, Hovencamp doesn't talk about
[20] reasonable accommodation. We can all pontificate about what
[21] we think it means, but to make a rule of law, make a
[22] statement that there's no explanation that's secondary, but
[23] yet there's no case law cited that anyone has ever used this
[24] standard, when to do so would mean to reject the Supreme
[25] Court case law of Masonite, new wrinkle lined material, as

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[1] well as the District Court cases here on the patent
[2] settlement cases seems to me to be a very bad way to make law
[3] or decide law.

[4] Your Honor, I want to come back to Cardizem and
[5] Terazeson because I want to talk about the way that the
[6] defendants distinguish it.

[7] JUDGE: Those District Court cases are pending
[8] appeal.

[9] MR. KADES: They are pending appeal.

[10] JUDGE: The two you've described, Cardizem and the
[11] other one.

[12] MR. KADES: Terazeson.

[13] JUDGE: Correct.

[14] MR. KADES: That one settled before it got in front
[15] of you.

[16] JUDGE: I know about Cardizem.

[17] MR. KADES: In the face of the Cardizem decision and
[18] the Terazeson case, Schering has not paid the argument that
[19] those cases were incorrectly decided. They tried to
[20] distinguish them by saying in those cases, those weren't
[21] final settlements, and that makes it completely different.

[22] That's a distinction that doesn't make a lot of
[23] sense. It doesn't make a lot of sense, one, because actually
[24] in Terazeson there were two settlements. The settlement with
[25] Geneva was not a final settlement, but the settlement with

[1] Zenith was a final settlement.

[2] Now, the Court choose to conclude that these weren't
[3] settlements because they were anti-competitive, but it did
[4] resolve the litigation. It did give them the ability to
[5] enter prior to the end of the patent, so the distinction is
[6] not correct, one.

[7] Two, it still doesn't provide any support for their
[8] position because if it's true that Schering can pay Upsher
[9] \$60 million to stay off until 2004, then why should it, by
[10] the same principle, be that Hoechst could pay Andrx to stay
[11] off the market until the patent suit was resolved, a much
[12] shorter time and tied directly to the merits of the patent
[13] case.

[14] The District Court in that case said, No, you can't
[15] do that, you can't pay someone to walk away from competition.

[16] JUDGE: You're talking about the judge in Michigan?

[17] MR. KADES: Yes, the judge in Michigan, and the judge
[18] in the Terazeson case did the same thing. Today the problem
[19] with the defendant's rule of law everywhere you look you can
[20] find several cases where they reject it.

[21] Your Honor, the final point is what is the effect of
[22] the Upsher agreement? There is obviously the primary effect
[23] of delaying the entry of Upsher until 2001 in September, and
[24] then there is this second issue with whether that delay — the
[25] entry of Upsher delayed the triggering of the 180 days and

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[1] therefore blocked additional entrants.

[2] Let me start there by saying, let's talk a little bit
[3] about the status of the law. In some sense it's actually
[4] much simpler than has been conveyed, at least for the
[5] purposes of this case.

[6] What we know is at the time of the settlement back in
[7] June of '97, there was a Successful Defense requirement in
[8] the regulations. A District Court struck that down. That
[9] means that at least at that time, it was reasonably
[10] foreseeable that that District Court case would be upheld on
[11] appeal, the meaning of which would be Upsher keeps its 180
[12] days.

[13] We fast forward to today. The status of the law is
[14] — what we care about the law here, Upsher has the 180
[15] days. How do we know that? ESI has tentative approval, has
[16] not gotten final approval. As we've learned just recently on
[17] the FDA's web site, there's a company called Elon
[18] Pharmaceutical Research Company. They have tentative
[19] approval. They have not gotten final approval.

[20] So until somebody — the way to know if Upsher has
[21] the 180 days, it's actually fairly simple. If there are
[22] people with tentative approval who haven't gotten final
[23] approval, it's because Upsher has the 180 days, and they
[24] haven't triggered it.

[25] JUDGE: Are you sure there can be no other reason —

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[1] I put to you that a consumer is going to reject that
[2] settlement because the consumer is getting nothing out of
[3] that settlement. They're just getting a delay that goes
[4] beyond what would be expected, and that, Your Honor, is
[5] why — the danger of the rule here is that if it's really the
[6] case that a monopolist who has a patent can always pay off
[7] potential entrants, they will always do so because the
[8] monopolist loses more from entry than the generic entrant
[9] gains.

[10] So they can make the generic better off than the
[11] generic can get by entry, and the result is that cases won't
[12] be tried because it's in their mutual interest not to try the
[13] case, to extend the monopoly and share the profits between
[14] the brand and the generic.

[15] The rule here is basically that — the rule proposed
[16] by Schering is basically a wholesale advocacy of antitrust
[17] law in the realm of patents, just to say to have a patent
[18] gives you a right not just to exclude. It doesn't give you
[19] the right just to go to Court and win. It doesn't give you
[20] just the right to license or not license.

[21] It gives you the right to clear the field forever of
[22] all potential entrants because you can always pay them more
[23] than they can earn.

[24] JUDGE: Is it the Government's position it doesn't
[25] matter the point in time of the settlement, whether it was

[1] rigors of competition or unilaterally avoiding it, Geneva and
[2] Zenith both paid packs with Abbott to enhance their
[3] collective profits to the detriment of consumers.
[4] That is why that agreement was an antitrust
[5] violation. That is why the agreement alleged is an antitrust
[6] violation in this case, and that is why Your Honor should
[7] dismiss the motion — should deny the motion to dismiss.
[8] Unless you have any further questions, I've concluded
[9] my presentation.

[10] JUDGE: Not at this time, thank you.

[11] You're rising to rebut?

[12] MR. NIELDS: To ask for permission to rebut.

[13] JUDGE: Go ahead.

[14] MR. NIELDS: Thank you, Your Honor. First, in
[15] response to one of the Court's questions, the agreement
[16] between Upsher and Schering says absolutely nothing about
[17] 180-day day exclusivity rights, nothing. It is in that
[18] respect in sharp contrast to the Hoechst Andrx agreement.

[19] JUDGE: It's going to be a matter of fact, isn't it,
[20] counselor, that either that has the effect of keeping
[21] everyone else out or it doesn't, right?

[22] MR. NIELDS: That's true.

[23] JUDGE: No matter what we think the law is, The FDA
[24] and the Courts are trying to figure it out. There's a
[25] rulemaking proceeding at this time, but whether or not that

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[1] immediately after the patent suit was filed or whether it was
[2] after the case closed and the case had gone to the jury?
[3] Does it matter at all?

[4] MR. KADES: Not if there was a payment for delay.
[5] Under their rule, Your Honor, let's say Schering got wind of
[6] Upsher's developing a product, but Upsher hadn't filed its
[7] ANDA yet. Schering called up Upsher and said, Well, we think
[8] you're probably going to have an infringing patent, you're
[9] going to infringe our patent, and let's further assume that
[10] was a good faith belief, Schering can pay Upsher to stop
[11] developing the product.

[12] JUDGE: If they sue them under your scenario before
[13] they get the notice requirement from FDA, they don't get the
[14] 30-day delay.

[15] MR. KADES: That's correct, Your Honor. I was trying
[16] to get a point that their rule of law would make this
[17] hypothetical legal as well, which is an astounding position
[18] to take, I think, that you basically can also pay people who
[19] haven't finished developing a product not to compete.

[20] JUDGE: Did I say 30-day again? 30 month.

[21] MR. KADES: Yes. I've tripped enough that I'm not
[22] one to point out those miscues.

[23] Your Honor, in conclusion, I want to turn back to the
[24] Terazoson case. And in the Terazoson case, the Court said
[25] this about the agreement. Well, instead of breaking the

[1] effect rose out of the agreement is going to be a factual
[2] matter.

[3] MR. NIELDS: A Government decision. It's going to be
[4] a Government decision. But still I want to add this thought,
[5] which is at least tangentially relevant. Regardless, if
[6] Upsher ever had any or ever has any exclusivity rights, it
[7] has been free at all times to transfer them to whoever.
[8] They could sell them for money, in sharp contrast to
[9] the Hoechst Andrx agreement whereas part of the agreement,
[10] Andrx agreed not to otherwise comprise any right including
[11] its right to its 180-day exclusivity period.

[12] There the private parties tried to make an agreement
[13] over this issue and to effect the rights that the parties
[14] would otherwise have had.

[15] Schering and Upsher didn't do anything like that.

[16] This is 100 percent a Government decision.

[17] JUDGE: Do you agree that none of the other companies
[18] have been granted the right by the FDA to sell this generic
[19] because of this 180-day or this exclusivity period?

[20] MR. NIELDS: I do not know the answer to that, Your
[21] Honor. You asked the question of complaint counsel whether
[22] there was any other reason for it, and he eventually said he
[23] didn't — none that he knew of.

[24] I don't know of any. I do know this, that Upsher was
[25] told it had exclusivity rights in a letter that FDA sent